

Food and Drug Administration, HHS

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ethylisobutrazine hydrochloride per pound of body weight to effect.¹

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.870 Etodolac.

(a) *Specifications.* Each milliliter contains 100 milligrams (mg) etodolac.

(b) *Sponsor.* See No. 000010 in § 510.600 of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 4.5 to 6.8 mg/pound (10 to 15 mg/kilogram) body weight as a single, dorsoscapular subcutaneous injection. If needed, the daily dose of etodolac tablets as in § 520.870 of this chapter may be given 24 hours after the injection.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 51365, Sept. 7, 2007, as amended at 75 FR 10167, Mar. 5, 2010]

§ 522.883 Etorphine hydrochloride injection.

(a) *Chemical name.* 6,7,8,14 - tetrahydro - alpha - methyl - alpha - propyl - 6,14 - endo-ethenooripavine-alpha-methanol hydrochloride.

(b) *Specifications.* Each milliliter of etorphine hydrochloride injection, veterinary, contains 1 mg of etorphine hydrochloride in sterile aqueous solution.

(c) *Sponsors.* See No. 053923 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is used for the immobilization of wild and exotic animals.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) It is administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(3) Do not use the drug unless diprenorphine hydrochloride injection, veterinary, as provided for in § 522.723, is available for use in reversing the effects of etorphine hydrochloride injection, veterinary.

(4) For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 16241, Apr. 15, 1983; 61 FR 260, Jan. 4, 1996]

§ 522.900 Euthanasia solution.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061, 051311, and 054925 for use of product described in paragraph (a)(1) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements: "ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife."

(d) *Conditions of use in dogs—(1) Indications for use.* For humane, painless, and rapid euthanasia.

(2) *Amount.* One mL per 10 pounds of body weight.

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(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 42969, July 21, 2003, as amended at 68 FR 55824, Sept. 29, 2003; 70 FR 8929, Feb. 24, 2005; 71 FR 13542, Mar. 16, 2006]

§ 522.914 Fenprostalene solution.

(a) *Specifications.*—(1) *Cattle.* Each milliliter of sterile solution contains 0.5 milligram of fenprostalene.

(2) *Swine.* Each milliliter of sterile solution contains 0.25 milligram of fenprostalene.

(b) *Sponsor.* See 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.277 of this chapter.

(d) *Special considerations.* Labeling shall bear the following statements: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. It is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(e) *Conditions of use.*—(1) *Cattle.*—(i) *Amount.* 1 milligram (2 milliliters) subcutaneously per animal.

(ii) *Indications for use.* For feedlot heifers to induce abortion when pregnant 150 days or less. For beef or nonlactating dairy cattle for estrus synchronization.

(iii) *Limitations.* Subcutaneous use in cattle only. Feedlot heifers to induce abortion, single dose. Beef or nonlactating dairy cattle for estrus synchronization, a single dose or two doses 11 to 13 days apart. Do not use in pregnant animals unless abortion is desired. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine.*—(i) *Amount.* 0.25 milligram (1 milliliter) subcutaneously once per animal.

(ii) *Indications for use.* For sows and gilts pregnant at least 112 days for the induction of parturition.

(iii) *Limitations.* Subcutaneous use in swine only. Federal law restricts this

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drug to use by or on the order of a licensed veterinarian.

[48 FR 7164, Feb. 18, 1983, as amended at 49 FR 26715, June 29, 1984; 54 FR 400, Jan. 6, 1989; 61 FR 5506, Feb. 13, 1996]

§ 522.930 Firocoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) firocoxib.

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses.*—(1) *Amount.* Administer 0.04 mg/pound (lb) (0.09 mg/kilogram (kg)) of body weight (BW) intravenously, once daily, for up to 5 days. If further treatment is needed, firocoxib oral paste can be administered at a dosage of 0.045 mg/lb (0.1 mg/kg) of BW for up to an additional 9 days of treatment.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 59611, Sept. 28, 2010]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 300 milligrams (mg) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin.

(2) 300 mg florfenicol in the inactive vehicle n-methyl-2-pyrrolidone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i) and for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use.*—(1) *Cattle.*—(i) 300 mg/mL florfenicol in 2-pyrrolidone and triacetin (inactive vehicles).

(A) *Amount.* 40 mg/kilogram (kg) body weight as a single subcutaneous injection.

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and nonlactating dairy cattle.